

REMARKS/ARGUMENTS

Claims 1, 2, 5-17, and 19-21 were examined and rejected. Claims 1, 5, and 6 have been amended. Claims 3, 4, and 18 stand withdrawn. Applicants believe independent claim 1 is generic. Re-examination and reconsideration of pending claims 1-21 is respectfully requested.

As an initial matter, Applicants request that the Examiner send confirmation of the consideration of the references cited in the Information Disclosure Statement filed by Applicants on September 5, 2001.

Rejections under 35 U.S.C. §102

Claims 1, 8-17 and 19-21 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,951,458 issued to Hastings et al. Claims 1-2 have been rejected under 35 U.S.C. §102(e/f) as allegedly being anticipated by U.S. Patent No. 6,390,967 issued to Forman et al. Such rejections are respectfully overcome in part and traversed in part as follows.

To more clearly claim the present invention as well as expedite prosecution of the present case, independent claim 1 has been amended. Claim 1 now recites a catheter comprising a catheter body, an ionizing radiation source, a source of at least one radiosensitizer, and means for releasing the radiosensitizer. This positive recitation of a source of at least one radiosensitizer has not been reasonably shown or suggested by the cited art.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. §2131; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

The Hastings et al. reference fails to teach a source of at least one radiosensitizer, much less means for releasing a radiosensitizer, as presently claimed by claim 1. Hastings et al. is instead directed toward a catheter that delivers oxidizing agents to blood vessel walls as a means of inhibiting restenosis. Specifically, Hastings et al. describes the use of hydrogen peroxides as the oxidizing agent. As the peroxide decomposes, hydroxyl ions are created which then damage, kill, or prevent the smooth muscle cells from multiplying thus significantly inhibiting restenosis. Col. 17, lines 60-64. With respect to the Forman et al. reference, Applicants concede that the Forman et al. patent teaches a radiation delivery catheter with shields. The present invention, however, now requires the positive limitation of a source of at least one radiosensitizer.

“Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *Scripps Clinic & Research Found. v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). Applicants request that if the present rejection is maintained, the Examiner show or explain where the Hasting et al. or Forman et al. patent references, alone or in combination, describe or suggest such radiosensitizer limitations. Absent such a showing, Applicants respectfully request withdrawal of these rejections and allowance of independent claim 1 (and dependent claims 2-21).

Claim Rejection under 35 U.S.C. §103

Claims 5-7 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hastings et al. in view of U.S. Patent No. 6,176,842 issued to Tachibana et al. This rejection is respectfully traversed.

Dependent claims 5-7 are in condition for allowance as they depend on allowable independent claim 1, which is discussed above in detail. These claims are further allowable as no suggestion or motivation, either in the cited references or in the knowledge generally available to one of ordinary skill in the art, has been cited by the Examiner for the proposed

combination of the reference teachings so as to produce the claimed invention as required for a *prima facie* showing of obviousness. M.P.E.P. § 2143.01; *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

The Examiner has already acknowledged that Hastings et al. fails to disclose "a source of at least one radiosensitizer." Office Action, page 4. The Tachibana et al. reference fails to teach any radiation modalities. The Tachibana et al. patent in contrast is directed to activating a certain class of drugs, particularly light activated drugs, via ultrasound energy for inhibiting tumor growth. Applicants request, if the present rejection is maintained, that the Examiner show or explain where the cited references provide the requisite motivation to combine any of these teachings so as to produce Applicants' claimed device.

The Examiner asserts that the "motivation for the incorporation would have been in order to enhance the application of the invention of Hastings." Office Action, page 4. Applicants point out that the Examiner bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness: *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976); M.P.E.P. § 2142. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* In the instant case, the Examiner has not pointed to any evidence in the reference teachings themselves which teaches or suggest their combination. See *In re Zurko*, 59 U.S.P.Q.2d 1693 (Fed Cir. 2001) ([I]n a determination of patentability the Board cannot simply reach conclusion based on its own understanding or experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings). Hindsight reconstruction is not permissible.

Per the references cited in this case, Applicants were the first to recognize the advantageous effects that may be achieved by a combined radiation therapy and radiosensitizer delivery catheter to inhibit hyperplasia. In particular, such a combination may reduce and/or inhibit hyperplasia with increased efficiency. For example, in some instances the radiation dosage may provide an immediate inhibition while the radiosensitizer may provide a prolonged inhibition. Furthermore, a combined balance of both therapies allows for reduced dose

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concentrations of radiation and/or radiosensitizers in the body lumen, as compared to relying on a single therapy. Hence, for these additional reasons, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be removed and that dependent claims 5-7 be allowed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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